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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,421	11/21/2003	John Eric Peckham	S63.2-11294-US01	3394
499 7590 09/18/2008 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344				
EXAMINER				
CHENG, JACQUELINE				
ART UNIT		PAPER NUMBER		
3768				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/719,421

Applicant(s)

PECKHAM, JOHN ERIC

Examiner

JACQUELINE CHENG

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27, 36 and 37 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-27, 36 and 37 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed March 11, 2008 have been fully considered but they are not persuasive. The examiner respectfully disagrees with the applicant's arguments that there is no teaching in Lee (US 5,203,777) or Kittrell (US 4,718,417) that would provide a rational to replace Lee's foil areas with a wire shaped according to the boundary of the foil areas. Firstly, the examiner would like to argue that Lee does not clearly teach that the embodiment of the rectangle marker must be a rectangular filled area. The applicant argues that that Lee seems to prefer a filled area of metal foil as it "is a provision of a marker system which has maximum visibility in a in a fluoroscopic or X-ray film image". The examiner agrees with the fact that the preferred embodiment of Lee is probably a filled area, however this is just one of the embodiments disclosed. Lee also discloses that other shapes can be used as long as they fulfill the same function of providing a way to determine rotational orientation (col. 7 line 67-col. 8 line 2). The examiner turns to fig. 4 of Lee to show that a hollow rectangle provides the same function as the filled rectangle. In fig. 4, in order to demonstrate how the rectangle marker is used to determine rotational orientation, only the rectangular boundary is shown. Although, true that fig. 4 does not necessarily teach that the markers are outlines of a rectangle, in the same respect fig. 4 also does not necessarily teach that the markers have to be filled areas excluding them from being outlines of a rectangle. Fig. 4 shows that either a filled rectangle or just a boundary of one can be used in Lee, as either fulfills the function (functional equivalents).

2. As to the applicant's arguments that an area of metal foil (filled rectangle) would appear different from a wire loop (outline of the rectangle) under fluoroscopy, the examiner acknowledges this fact, however Lee discloses that multiple shapes can be used such as a letter E as illustrated in fig. 7a of Lee. Therefore the fact that a filled rectangle appears different from a rectangle outline does not preclude Lee from teaching using a wire loop. A wire loop (rectangle outline) can fall under one of these other multiple shapes that Lee discloses can be used. The examiner believes the wire loop is not unlike the marker in the shape of the letter E, which does not have a filled region and is created from four lines, like a wire loop. Furthermore, the examiner believes that this shape would have the same visibility as an outlined rectangle.

3. In regards to using a wire marker versus one made of foil, the examiner would like to point out that Lee only uses foil as an example of what the radiopaque markers can be made from, stating that "the radiopaque markers can be made from a suitable conventional metal or the like" and that "...the markers 60 and 62 *can* comprise squares of gold foil or the like" (col. 5 line 9-14). They do not have to be made of foil. Therefore, especially if the marker has a shape such as the letter E or a rectangle border, it would be obvious to use a wire shaped metal, such as taught in Kittrell as being a material that provides radiopacity and which taught as being a common material to use as a marker (the secondary use of the wire marker to reinforce a joint having no relevance to the wire being used as a radiopaque marker), as a suitable conventional metal for the radiopaque marker of Lee.

4. The examiner would also like to argue that besides a marker made of wire and a marker made of foil being functional equivalents, that choosing between the two is a design choice. The applicant has not disclosed that using a wire as the marker cant does not explicitly disclose the

importance of using a wire as the marker provides a particular advantage. In fact the applicant admits in their specification on line 19-20 of page 13 that either strips (which could be strips of metal foil) or wires can be used to determine the rotational orientation of the device.

5. Therefore for these reasons above the examiner believes that it would be obvious to combine Lee in view of Kittrell and that the rejection dated December 12, 2007 still stands. This rejection along with a new rejection (in italics) in response to amendments of claim 11, 14, and 22 (in view of Armstrong 2002/0099431 A1) is stated below.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-10, 12, 15-21, 23-27, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 5,203,777) in view of Kittrell (US 4,718,417).

8. **Claims 1-10, 12, 24-27, 36, 37:** Lee discloses a medical device and a radiopaque marker that is permanently coupled to a medical device, which can be any known medical device in the art such as a catheter, an ultrasound device, a cannula, or basically any device that has a body which is tubular in form and has a distal end and outer periphery, of which a catheter sheath, stent of any form, and an expansion balloon fall under. This marker is a radiopaque marking system used to determine the rotational position of the medical device using an imaging device

when the medical device is positioned within a body lumen. The markers are viewed in an image and then the medical device is positioned in the desired orientation. Lee discloses that the markers are rectangular in shape, and be made from a suitable conventional metal or the like (abstract, col. 3 line 46-52, col. 5 line 5-10). Although Lee does not explicitly disclose that this metal is shaped into a wire, it is obvious to one skilled in the art to use wires as the marker on a medical device as can be seen in Kittrell. Kittrell teaches using radiopaque markers in the shape of a metal band or wire (col. 9 line 29-42). So if wire was chosen to be used as the marker material of Lee, it would mark the boundary of the enclosed rectangle (creating a loop), having a first portion that extends in a circumferential direction, a second portion that extends in a direction parallel to the longitudinal axis, a third portion extending in a circumferential direction again, and a fourth second extending in a direction along the longitudinal axis (fig 2). It would be obvious to one skilled in the art to substitute a wire material instead of a metal foil material as they are functionally equivalent and will obtain predictable results. Having a hollow rectangle vs a filled rectangle would not change one's ability to determine the rotational direction the medical device is positioned in. In fact, in fig. 4 the rectangles are drawn as just having an outline, showing that the rectangle does not have to be filled in to interpret the markers. Although Lee does disclose that the metal foil (filled in rectangle) is used to maximize visibility, Lee also discloses that for larger medical devices and other types of devices other shapes can be used to fulfill the same function (col. 7 line 64-col. 8 line 5).

9. **Claims 15-21 and 23:** Lee discloses that other variations of markers besides a substantially square marker can be used. An example that Lee gives is using directional indicators which forms a symbol of an "E", which has a first portion in a circumferential

direction and a second portion in a direction parallel to the longitudinal axis and provides directional indicators in a form direction non-parallel to the longitudinal axis (the first and second (and a third) directional indicators that form a symbol being the stems of the E). Also although Lee does not explicitly disclose an example of a marker as being an arrow, it is well within the boundaries of one skilled in the art to use an arrow marker, as it shows direction and also would be able to show rotational orientation. As to the symbol being viewable over a rotational range of 35 degrees or less, as you can see in fig. 4 as the catheter is being rotated 45 degrees from the 0 degree position the marker 60, which in a different embodiment could be the E or an arrow symbol can is still viewable.

10. **Claims 13** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Kittrell further in view of Pacetti (US 6,574,497 B1). Although Lee discloses that the marker coupled to the medical devices is a radiopaque marker it would be obvious to one skilled in the art at the time the invention was made to use a marker that would viewable in whichever type of imaging device is being used. In a case where using an x-ray imaging device is not ideal, an MRI device can be used. In such a case the marker would have to be an MRI marker. Pacetti discloses such a case wherein x-ray fluoroscopy is the preferred imaging modality for procedures such as cardiovascular procedures, but it may not be ideal for various reasons such as the ionizing x-rays are dangerous, so may not be ideal for patients who has repeated interventions. In such a case using an MRI device and MRI markers would be much more ideal (col. 1 line 13-39, col. 3 line 3-60).

11. *Claims 11, 14, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Kittrell further in view of Armstrong (US 2002/0099431 A1). Lee discloses that any type of medical device can be used, so it would therefore be obvious to use a stent-graft device such as disclosed by Armstrong. Armstrong discloses a stent which is covered by either a partial or a full graft wherein the stent graft is aligned with an radiopaque marker. The radiopaque marker can be any type of radiopaque marker such as the one disclosed by Lee (paragraphs 0016, 0025, 0097, 0104).*

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/
Supervisory Patent Examiner, Art Unit
3737

JC